Study Title: Managing Pain and Cognitions in Older Adults With Mild Cognitive Impairment or Memory Related Problems and Chronic Pain

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STATISTICAL DESIGN AND POWER

The present proposal aims to adapt, pilot and examine the credibility, acceptability, adherence and feasibility of the p3RP and the p3RP-DMD adapted for patients with MCI (Active Brains and Active Brains with Fitbit). We have already developed the p3RP and p3RP-DMD which are adapted for the specific needs of patients with chronic pain, but not MCI. The proposed R34 supplement feasibility project will lay the groundwork for a large RCT of the Active Brains vs Active Brains with Fitbit vs attention placebo control, and will help understand whether the DMD Fitbit is feasible and necessary to comprehensively improve function. Consistent with prior theory within a subsequent efficacy trial` we will test the hypothesis that the Active Brains with Fitbit will be superior to the Active Brains and HEP in improving and sustaining improvements in objective, performance based and self-reported physical and emotional function in patients with heterogeneous chronic pain comorbid with MCI. Using the supplement to the R34 mechanism we will follow an iterative design 82,83 to adapt and refine both the p3RP and the integrated p3RP-DMD interventions to maximize feasibility, acceptability, credibility, recruitment protocol, adherence and measurements for patients with heterogeneous chronic pain. To allow objective measurement of activity in both Active Brains and Active Brains with Fitbit groups, we will use Accelerometer DMDs for 1 week at baseline and post-test. The Fitbit DMD will be used to address/reinforce activity consistent with an individualized pacing plan, and to assess daily activity during the program only for those randomized to the Active Brains. All procedures have already been piloted within our R34 and will easily be adapted for the supplement.

Power analyses:

This trial (Aim 2) is primarily focused on feasibility and acceptability, not statistical significance of efficacy. With a sample size of N=60 participants the study will have 80% power to confirm feasibility of each delivery modality if the true completion rate among eligible patients is at least 77%, much lower than the 100% retention we achieved in our preliminary studies15,16 of the 3RP in a different population.

Analyses plan:

Aim 1. We will report feasibility as number of screened, eligible participants, and enrolled particpants, and number of participants who completed at least 6 out of the 8 sessions. We will also report information on preliminary acceptability from quantitative and qualitative data, as well as information on credibility of intervention and adherence to DMD and Active Brains homework. We will also calculate descriptive statistics for quantitative measures. Qualitative Data Analyses: The qualitative focus group data and individual exit interview data will be transcribed and analyzed, using NVivo 10 qualitative software, and we will conduct thematic content analysis using guidelines provided by Miles and Huberman (1984)99. The 2 coders (study clinician and research assistant) will meet on an ongoing basis with Dr. Vranceanu to discuss the structural thematic framework, categories, and coding plan. To ensure coding reliability, coding discrepancies will be resolved through discussion and comparison of raw data. Coding will continue until a high reliability (Kappa= >0.80) is established. Once these data analyses are completed, the multidisciplinary team will provide the expert review of data, to discuss the interpretation of our findings in the context of current research on chronic heterogeneous pain. The same method was used successfully in our R34 grant.

Aim 2. To test in a small RCT pilot (N = 60 participants, 6 groups, 30/arm) the refined Active Brains with Fitbit versus Active Brains using the final adapted treatment manuals in preparation for a large RCT. We will report comparatively feasibility, credibility, acceptability and adherence between the 2 treatments. Feasibility will be assessed as depicted in the prior section. We will calculate the proportion of patients who complete at least 6 of the 8-planned treatment sessions (75%), along with the 95% confidence interval (CI) around this discontinuation rate. Treatments are considered feasible if over 70% of participants complete at least 6 treatment sessions. Adherence to treatment manual: We will assess adherence to treatment by listening to the audio recorded sessions, completing and analyzing the therapist adherence checklists. We will also rate adherence of study clinician in phase 2. The therapists will also

complete session adherence checklists. Adherence to Accelerometer and Fitbit DMD: We will report number of days participants in both groups wore the Accelerometers at baseline and at post test, and average number of days the FitBit was used in the p3RP-DMD group. The main purpose of our RCT is to compare feasibility, acceptability, credibility and adherence of the Active Brains with Fitbit and Active Brains. The trial is neither powered for efficacy nor aimed to provide such information. Justification for the sample of 30/group is depicted in the power consideration section. Consistent with the feasibility design of this trial, we will report means and SDs of all measures at all time points, including distribution of scores and internal consistency reliability. To determine the measures' sensitivity to detect change, we will report percent change in all quantitative outcomes within each group. Outcomes are: physical function/activity (self reported physical function and physical activity scales total scores, distance walked during the 6 minute walk test, and average number of steps and active minutes), emotional function (depression and anxiety), coping (catastrophizing, fear avoidance and coping style) and pain intensity. We will also describe types of activity (e.g., light, moderate and vigorous) and sedentary time as measured by the Accelerometers at pre and post in both groups. Within the Active Brains with Fitbit group, we will explore patterns of increased numbers of steps and active minutes daily, patterns of activity versus sedentary time, and number of blocks achieved. We will also summarize demographic and clinical variables. We will not conduct any efficacy analyses consistent with the R34 mechanism and prior research recommendations24,25 .